

**REMARKS**

The Examiner is thanked for the due consideration given the application.

Claims 1-5 and 8-22 are pending in the application. Claims 1, 2, 15 and 16 have been amended to improve the language in a non-narrowing fashion. Claims 20 - 22 are newly presented.

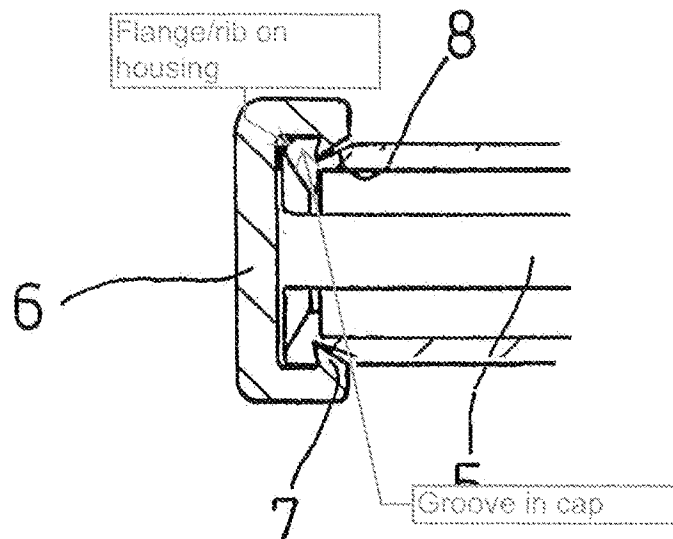
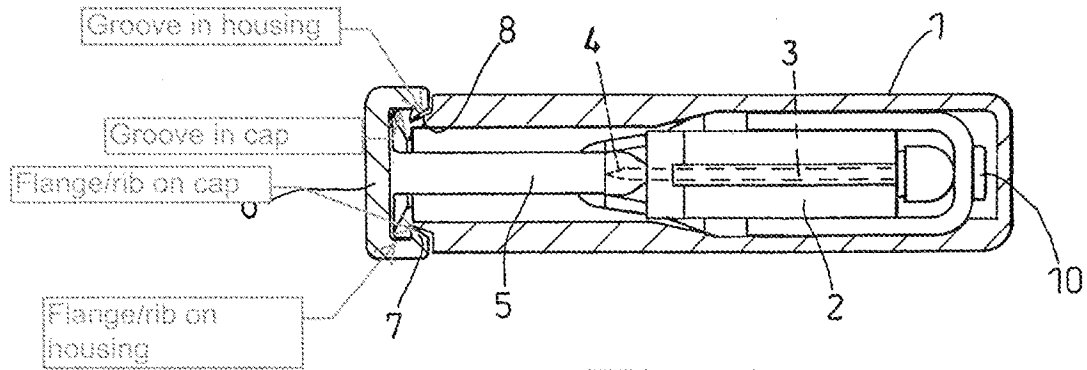
No new matter is believed to be added to the application by this amendment.

**The Drawings**

The drawings have been objected to as not showing all the features ("vice versa") of claims 2 and 16.

Claims 2 and 16 have been amended to described the fitting together as "*wherein the at least one locating member ~~b~~ and the at least one cooperating feature are fitted together via a groove cooperating with a flange or a rib.*" This embodiment of the present invention is clear in light of the instant drawing figures.

In fact, the instant drawing figures actually illustrate both arrangements. At first sight, and as described, the cap 6 in Figure 3 has flanges 7 which are received in grooves or notches 8 in the wall of the housing. However, of course, the notches 8 actually define a rib on the front end of the housing which is received in a groove defined in the space between the flat end wall of the housing and the housing flanges.



Alternately, it is noted that the technology of a flange/rib cooperating with a groove is known in the art to the extent that one of skill could practice the present invention without recourse to a drawing figure.

Withdrawal of this objection to the drawing figures is accordingly respectfully requested.

**Rejection Under 35 USC §112, Second Paragraph**

Claims 1-5, 8-10 and 15-19 have been rejected under 35 USC §112 second paragraph as being indefinite. This rejection is respectfully traversed.

The Official Action asserts that the utilization of the term "whereby" in claims 1 and 15 renders the claims unclear.

However, the claims have been amended to recite: "**and** the cap holds the lancet against movement relative to the housing." It is submitted that, read in normal fashion, the claimed limitations are entirely clear, namely that the combination (a) of the cap extending to project from an attachment to the lancet through an opening at one end of the housing and (b) having at least one locating member fitting into at least one cooperating member of the outer walls of the housing, results in the consequence that the cap holds the lancet against movement relative to the housing.

The Official Action asserts that the term "vice versa" in claims 2 and 16 is unclear. However, these claims have been amended to clearly set forth "*wherein the at least one locating member ~~is~~ and the at least one cooperating feature are fitted together via a groove cooperating with a flange or a rib.*"

The claims are thus clear, definite and have full antecedent basis.

### **Art Rejections**

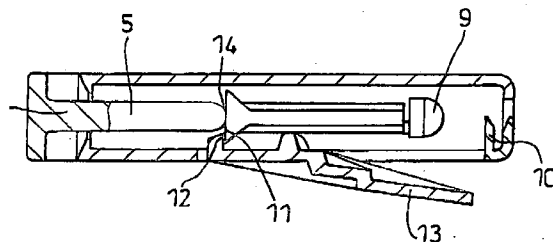
Claims 1, 2, 11 and 12 have been rejected under 35 USC §102(b) as being anticipated by KOIKE (WO 03/005907, relying upon by U.S. Publication 2004/0243165).

Claims 4, 5, 8, 10, 15 and 16 have been rejected under 35 USC §102(b) as being anticipated by MARSHALL (U.S. Patent 5,487,748) in view of KOIKE.

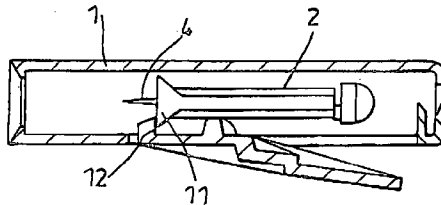
Claims 3, 9, 13, 14 and 17-19 have been rejected under 35 USC §102(b) as being anticipated by KOIKE or MARSHALL in view of KOIKE, and further in view of HAYNES (U.S. Patent 3,165,220).

These rejections are respectfully traversed.

The present invention pertains to a blood sampling device that is illustrated, by way of example, in Figures 5 and 6 of the application, which are reproduced below.



***Fig. 5***



***Fig. 6***

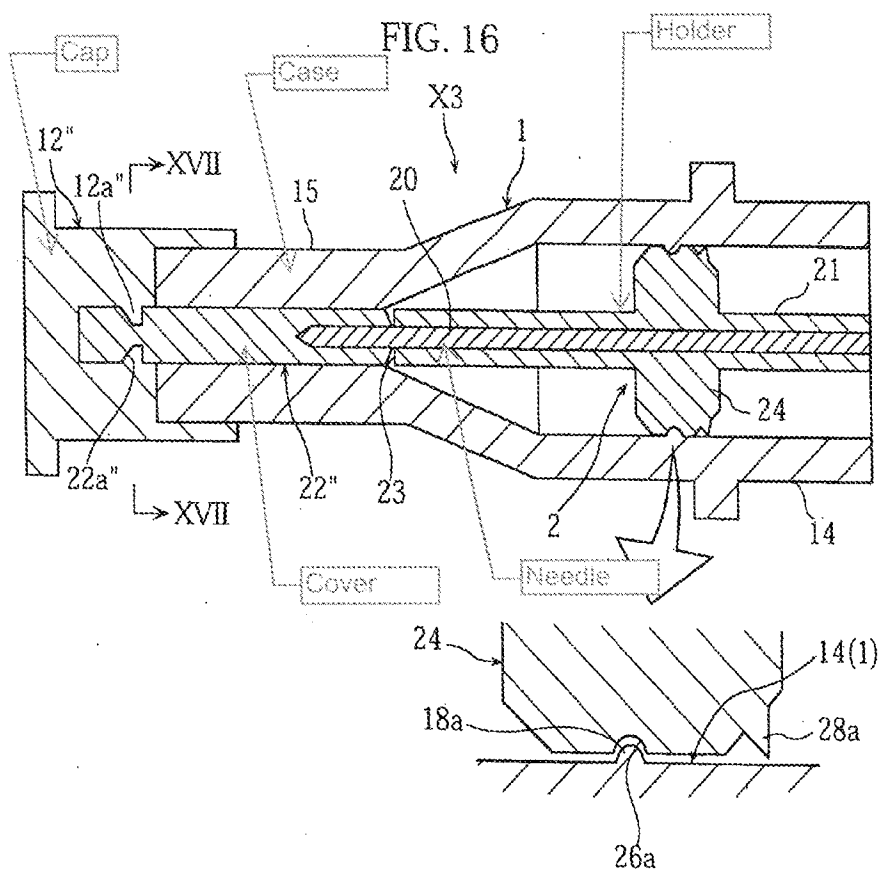
In the present invention, the cap 5 is releasably attached to the lancet 2 adjacent the needle 4 and extends from its attachment to the lancet to pass through an opening in the housing of the device, the cap 5 and housing 1 cooperating so that the cap 5 holds the lancet 2 against movement relative to the housing 1.

Claim 1 of the present invention recites: "*the cap being twistable to release the at least one locating member from the at least one cooperating feature such that the cap can be detached from the housing and from the lancet.*"

That is, in the claimed device, the cap is releasably attached to the lancet adjacent the needle and extends from its attachment to the lancet to pass through an opening in the housing of the device, the cap and housing cooperating so that the cap holds the lancet against movement relative to the housing.

Regarding KOIKE, the applicant has not carried out an assessment as to whether the U.S. document is a faithful reproduction of the Japanese document, and the applicant therefore does not admit that the two are identical.

The Official Action particularly points out the lancet illustrated in Figure 16 of KOIKE, an annotated version of which is reproduced below.



Also note Figures 18(b) and 18(c) of KOIKE, which are reproduced below.

FIG. 18B

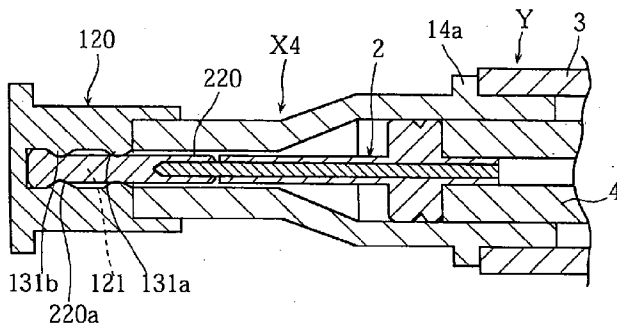


FIG. 18C

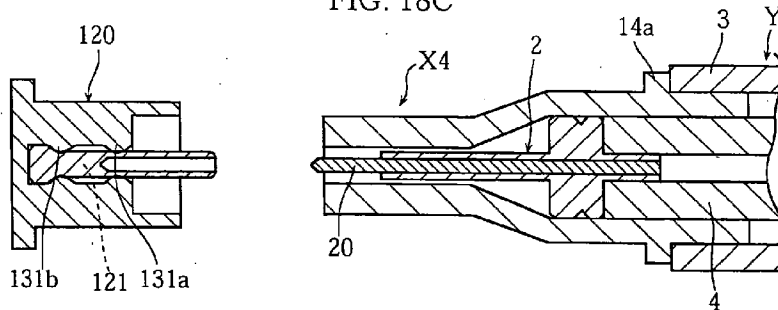
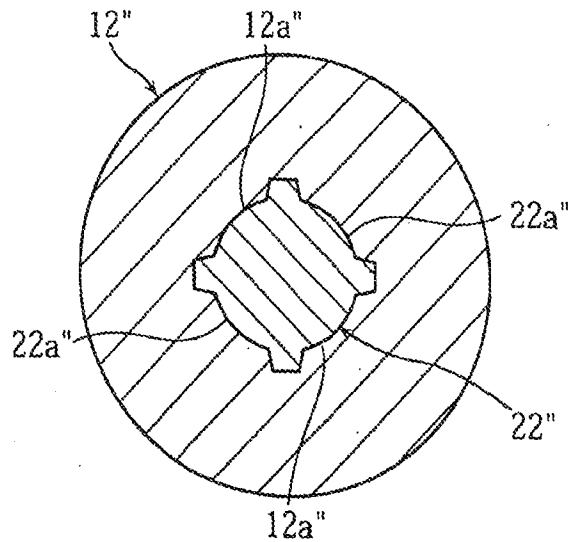


Figure 16, along with Figures 18(b) and 18(c) show the cap removal action of an embodiment which is 'basically similar' to that of the Figure 16 lancet (see paragraph [0098] of KOIKE. In the arrangement of KOIKE, a lancet holder 21 with a needle 20 is housed within a case 1. The needle tip is covered by a cover portion 22 which is connected to a cap 12'' (as explained in paragraph [0094]) and as illustrated in the cross section of Figure 17 (reproduced below), the cap and the cover have complementary projections and recesses so that the cap and cover move in unison. As noted by the Examiner, paragraph [0088] makes it clear that the cover portion and the cap are removed (from the casing) by exerting a rotational force and a pulling force onto the cap 12.

FIG. 17



There are numerous significant differences between this arrangement and that defined in independent Claims 1, 11 and 15 of the present invention. Specifically, the cap 12 of Koike et al is not releasably attached to the lancet adjacent its needle; instead, the cap is non-releasably attached to the cover which itself is releasably attached to the lancet adjacent its needle.

The cap does not extend, from an attachment to said lancet, to project through an opening at one of the housing; the cap does not project at all through an opening in the housing but instead the cap is attached to the cover and the cover extends through an opening in the housing.

The cap does not have a locating member which fits into a cooperating feature of outer walls of the housing; the cap does not have any such features but merely fits over the end of the

housing, having what appears to be a cylindrical bore which slides over the cylindrical outer surface of the housing.

The Official Action appears to equate the locating member of Claim 1 with the cover 22'', but even taking this interpretation, the arrangement of KOIKE does not provide an arrangement in which the locating member can be removed from the cooperating feature to detach the cap from the housing and the lancet.

Even if, for the sake of argument, this interpretation were applied, there is no interaction between the cover 22'' and the outer walls of the housing. That is, the cap holds the lancet against at least forward movement relative to the housing. See new claims 20 and 21.

In summary therefore, KOIKE has a cover attached to the lancet which projects out of the casing to carry a cap. The cap does not attach to the lancet itself and the cap does not have a locating member which fits into at least one cooperating feature of outer walls of the housing.

Similarly, Claim 2 is distinguished because the features discussed in Claim 2 relate to a feature on the cap and a feature on the housing, the features the Official Action refers to are features on the cap 12'' and the cover 22''.

Similar observations apply in relation to Claim 11. KOIKE does not disclose a cap having a first end releasably attached to the lancet body and a second end that is releasably

attached to the housing by a locating member that fits into a cooperating feature on the outer wall of the housing.

Now consider MARSHALL. The Official Action argues that MARSHALL is a cap which is "adapted to hold the lancet in a position in which the lancet latch surface is spaced rearwardly of the latch surface of the trigger releasable latch until said cap is detached from the lancet (see Figure 1)." Figure 1 of MARSHALL is reproduced below.

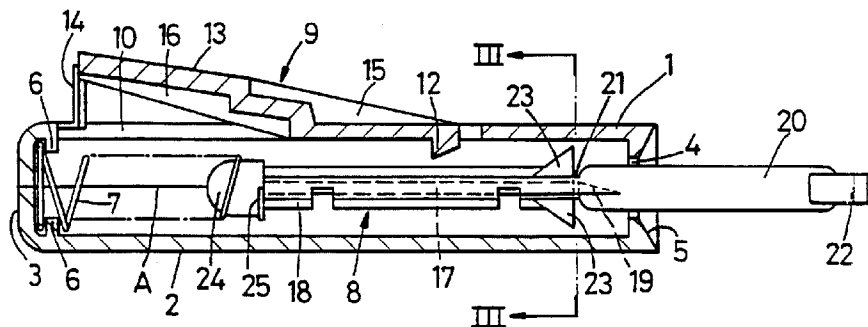


Fig.1

In Figure 1 of MARSHALL the lancet latch 23 is spaced some way **forwards** of the trigger releasable latch 12. Furthermore, the cap is not adapted in any way to hold the lancet in a particular position.

The Official Action also argues that MARSHALL does not explicitly teach that the cap has at least one locating member etc. To be quite clear, there is no implicit or explicit teaching of any connection between the cap and the outer walls of the housing. As is clearly evident from viewing Figures 1 and 2, the cap is T-shaped with the stem passing through and over-size

opening 4 at the front end of the housing and there is no cooperation between the two. As already explained in relation to KOIKE previously, there is no arrangement in KOIKE of the cap having at least one cooperating feature which prevent forward movement of the needle relative to the housing prior to removal of the cap. Similar comments apply to Claim 16.

Turning now to HAYNES, this discloses a tamper proof container and relates to a cap for closing a container. There is no teaching of an arrangement for a device in which the cap fulfils any other function than closing the neck and certainly not an arrangement where the cap extends through the neck of the housing to interact with a mechanism inside the housing to prevent its operation. It would thus not have been obvious to combine the teachings of KOIKE or MARSHALL with HAYNES.

Finally, in relation to Claims 10 and 15, the feature of the cap holding a spring loaded lancet in a position in which the lancet latch surface is spaced rearwardly of the latch surface of the trigger releasable latch until after said cap is removed, performs one of the important functions of the present invention.

In order to have a light but reliable trigger action, the complementary latch surfaces on the housing and the lancet need to be designed so that they may be released by finger pressure on the latch. By contrast, the physical inter-engagement between the cap and the housing can be made

sufficiently robust and geometrically secure, e.g., by means of a re-entrant profile as evident from Figure 3. Were as is usual the components are made of plastic, if the latch surfaces are loaded for an extended period such as during storage for several months or years, the plastic can 'creep' under the sustained pressure of the spring. By providing an arrangement in which the cap holds the latch surfaces spaced apart, against the influence of the drive spring, until the device is ready to be used, the problem of creep of the latch surfaces is avoided.

Moreover, of course, the presence of the cap provides an important safety feature and also provides a visual indication of the state of the device.

As a result, the applied art neither anticipates the present invention nor renders the present invention prima facie unpatentable.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

#### **CONCLUSION**

Having addressed all the outstanding issues, the amendment is believed to be fully responsive. In view of the above, it is respectfully submitted that the application is in condition for allowance and notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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